the Inspector General published a report for the Department of Health and Human Services in 2000 documenting Novartis' inflated AWP for Aredia, its brand of pamidronate disodium.

10. Pfizer

325. Pfizer engages in an organization-wide and deliberate scheme to inflate AWPs. Pfizer has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Accupril	quinapril hcl	ACE Inhibitor (Cardiovascular Agent) Used in the treatment of hypertension
Cardura	doxazosin mesylate	Autonomic Nervous System Agent Used to treat hypertension and benign prostatic hypertrophy
Estrostep FE	norethindrone-ethinyl estradiol-fe	Oral Contraceptive Also used in the treatment of acne
Femhrt 1/5	ethinyl estradiol-norethindrone acetate	Estrogen Combination (Hormone) Used in the treatment of menopause and prevention of postmenopausal osteoporosis
Lipitor	atorvastatin calcium	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
Nardil	phenelzine sulfate	Antidepressant (Psychotherapeutic Agent) Used in the treatment of depression
Neurontin	gabapentin	Anticonvulsant Used in the treatment of epilepsy
Zithromax	azithromycin	Macrolide Antibiotic Agent (Anti-Infective Agent) General antibiotic
Zoloft	sertraline hcl	Serotonin Reuptake Inhibitor (Psychotherapeutic Agent: Antidepressant) Used in the treatment of depression
Zyrtec	cetirizine hcl	Antihistamine Used in the treatment of allergic rhinitis

326. The specific drugs manufactured and/or distributed by Pfizer for which relief is currently sought in this case are set forth below or in Appendix A.

327. Pfizer controlled and set the AWPs for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia.

328. Pfizer's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

a. Pfizer's understanding of AWP and intentional manipulation thereof

329. Pfizer has engaged in an ongoing deliberate scheme to inflate AWPs and to market the spread to increase the sales of its products.

b. Pfizer provided other improper incentives

330. In addition to marketing the spread, Pfizer has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, Pfizer provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

c. Pfizer has been the target of government investigations

331. Pfizer has been investigated by the Office of the Inspector General of the Department of Human Health Services and has entered into a $49 million settlement arising from illegal practices with respect to Lipitor. OIG-HSS found that Pfizer has been providing unrestricted educational grants and rebates that were in fact discounts off the purchase price of Lipitor. Pfizer concealed these discounts from states who were entitled to receive the "best price" for Lipitor.

332. The provision of educational grants and rebates on Lipitor also had the effect of inflating the reported AWP.

11. The Schering-Plough Group (Schering-Plough and Warrick)

333. The Schering Plough Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Schering Plough Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Clarinex	desloratadine	Antihistamine Used to relieve the symptoms of hay fever and hives of the skin
Claritin	loratadine	Antihistamine Used to relieve or prevent the symptoms of asthma
Claritin-D	loratadine & pseudoephedrine	Antihistamine Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever
Diprolene	aug betamethasone dipropionate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
Diprosone	betamethasone dipropionate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
Elocon	mometasone furoate	Antipruritic (Skin & Mucous Membrane Agent) Used to help relieve redness, swelling, itching, and discomfort of many skin problems
Eulexin	flutamide	Antineoplastic Used to treat cancer of the prostate gland
Integrilin	eptifibatide	Cardiovascular Agent Used in the treatment of patients with acute coronary syndrome
Intron-A	interferon alfa-2b	Immunomodulator Used in the treatment of hairy cell leukemia and chronic hepatitis B or C.
Lotrisone	clotrimazole w/ betamethasone	Antifungal Agent (Anti-Infective Agent) Used to treat fungus infections
Nasonex	mometasone furoate (nasal)	Anti-Inflammatory Agent (Nasal Preparation) Relieve the stuffy nose, irritation, and discomfort of hay fever and other allergies
Peg-Intron	peginterferon alfa-2b	Biological Response Modifier Used to treat chronic hepatitis C
Proventil	albuterol sulfate	Bronchodilator (Respiratory Agent) Used to treat the symptoms of asthma, chronic bronchitis, emphysema, and other lung diseases
Rebetol	ribavirin	Biological Response Modifier Used to treat hepatitis C
Sebizon	sulfacetamide sodium	Anti-Infective Agent Used in the treatment of conjunctivitis and other ocular infections
Temodar	temozolomide	Antineoplastic Used to treat a specific type of cancer of the brain in adults whose tumors have returned

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Trinalin Rep	azatadine & pseudoephedrine	Antihistamine Used to treat the nasal congestion, sneezing, and runny nose caused by colds and hay fever.
Vanceril	beclomethosone (nasal)	Anti-Inflammatory Agent; Antiasthmatic Used to help prevent the symptoms of asthma
	albuterol	Bronchodilator (Respiratory Agent) Used for relief of bronchospasm in asthma sufferers
	clotrimazole	Antifungal Agent (Anti-Infective Agent) Used to treat yeast (fungus) infections of the vagina
	griseofulvin ultramicrocrystalline	Antifungal Agent (Anti-Infective Agent) Used to treat fungus infections of the skin, hair, fingernails, and toenails
	oxaprozin	Central Nervous System Agent; Antipyretic (Analgesic) Used in the treatment of osteoarthritis and rheumatoid arthritis
	perphenazine	Antiemetic (Gastrointestinal Agent); Antipsychotic Agent (Psychotherapeutic Agent) Used to treat serious mental and emotional disorders. Also used to relieve moderate to severe pain in some hospitalized patients
	potassium chloride	Electrolytic Agent Used to prevent and treat potasium deficit secondary to diuretic or cortiocosteroid therapy
	sodium chloride	Flush; Abortifacient Used to remove medicine and blockage from intravenous (IV) catheter. Also used to induce abortion
	sulcrafate	Gastrointestinal agent Used for short term treatment of duodenal ulcer
	theophylline er	Bronchodilator (Respiratory Agent) Used to treat and/or prevent the symptoms of bronchial asthma, chronic bronchitis, and emphysema

334. The specific drugs manufactured and/or distributed by The Schering Plough Group for which relief is currently sought in this case are set forth below or in Appendix A.

335. The Schering Plough Group controlled and set the AWPs for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. For example, on February 23, 1995, Warrick sent a letter to First DataBank, stating:

> Effective Friday, February 24, 1995, at 5:00 p.m., the price of Warrick Albuterol Solution 0.5% 20ml will increase as follows:
>
> | | NDC 59930- | AWP |
> |---|---|---|
> | Albuterol Solution 0.5% 20 ml | 1515-04 | $13.95 |

(WAR0024086) (Highly Confidential).

336. The Schering Plough Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

a. The Schering Plough Group's understanding of AWP and intentional manipulation thereof

337. A Schering Laboratories memorandum dated May 20, 1993 demonstrates Defendant's recognition that intermediaries choose drugs based on favorable AWP spreads. At the generic launch of albuterol, Schering stated:

> Proventil will stay listed at AWP; therefore, Proventil is a favored product for third party reimbursement that provides for the AWP minus 10% reimbursement rate to chains. Thus, they can buy off the Proventil deal and bill at AWP.

(WAR005419-20) (Highly Confidential).

338. According to Warrick's own documents, Warrick consistently maintained a spread between the AWPs and the direct prices it offered for its albuterol products. For example, a "Price Change" alert dated June 7, 1999 sent to Warrick customers provides:

Product	Pkg. Size	NDC 59930	AWP	Direct Price
Albuterol Inhalation Aerosol	17 g	1560-1	$21.41	$3.40
Albuterol Aerosol Refill	17 g	1560-2	$19.79	$3.40

(WAR0000532) (Highly Confidential). Thus, Warrick touted a 529% spread on its albuterol inhalation aerosol and a 482% spread on the refill.

339. In a report to Congress, the GAO reported that albuterol sulfate was one of a small number of products that accounted for the majority of Medicare spending and volume. Albuterol sulfate accounted for 6.3% of total Medicare spending, ranking fifth out of more than

400 covered drugs. Albuterol sulfate ranked first for volume of units covered, accounting for 65.8% of total units reimbursed. *See* GAO Report to Congressional Committees, "Payments for Covered Outpatient Drugs Exceed Providers' Cost," Tables 1 and 2, pp. 7-8 (GAO-01-0118 (P005546-005578)). The Schering Plough Group is one of three companies noted by the DOJ as manufacturing albuterol. *See* DHHS report, AB-00-86 (P006299-006316).

340. According to The Schering Plough Group's own documents, the published AWPs for most of its drugs were higher than the actual prices provided to wholesalers.

341. In response to government subpoenas, The Schering Plough Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that Warrick has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1, 2 and 3 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Warrick drugs from a document entitled, "Amerisource" (WAR0022160) (Highly Confidential).

TABLE 1

LABEL (MFG)	GENERIC NAME	AWP	INVOICE COST	DIFFERENCE	PERCENTAGE SPREAD
Warrick	Albuterol Inhaler	21.41	5.75	15.66	272%
	Aug Beta Dip Oint 0.05%	43.20	26.90	16.30	61%
	Griseofulvin	82.47	37.22	45.25	122%
	Theophylline	11.70	2.83	8.87	313%

Table 2 is an analysis of certain dosages of Warrick drugs from a document entitled, "1997 Care Group Bid Proposal." (WAR0022122) (Highly Confidential).

TABLE 2

PRODUCT	**AWP**	**INVOICE PRICE**	**NET PRICE (AFTER REBATE)**	**DIFFERENCE BETWEEN AWP AND INVOICE PRICE**	**PERCENTAGE SPREAD**
Clotrimazole	22.25	7.77	6.99	14.48	186%
Perphenazine	78.00	19.53	17.58	58.47	299%

Table 3 is an analysis of certain dosages of Warrick drugs from a document entitled, "Managed Care Pricing," dated July 1, 2002. (WAR0054226) (Highly Confidential).

TABLE 3

Product	Minimum PBM/Mail Order/ Staff Price Guide	Target PBM/Mail Order/ Staff Price Guide	Minimum GPO Price Guide	Target GPO Price Guide	AWP	Difference	% Spread
ISMN	4.48	4.93	5.15	5.38	117.40	112.02	2,082%
Oxaprozin	11.42	12.56	13.13	13.70	117.40	103.70	757%
Potassium Chloride	9.67	10.64	11.12	11.60	65.00	53.40	460%
Sodium Chloride	6.12	6.73	7.04	7.34	24.30	16.96	231%
Sulcrafate Tablets	45.15	49.67	51.92	54.18	353.71	299.53	553%

342. Additional drugs and/or examples of AWPs that were phony and manipulated are identified below:

Manufacturer	Drug Name	NDC	Quantity	1999 AWP *Red Book*	W-Sale Spread	%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1500-06	3 ml 60s	72.60	48.60	202.5%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1500-06	3 ml 60s	72.60	47.34	187.4%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1500-06	3 ml 60s	72.60	56.10	340.0%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1500-08	3 ml 25s UD	30.25	20.25	202.5%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1500-08	3 ml 25s UD	30.25	19.72	187.3%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1500-08	3 ml 25s UD	30.25	23.30	335.3%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1515-04	0.5%, 20ml	14.99	9.48	172.1%
Warrick	Albuterol Sulfate (SOL, IH, 0.083%)	59930-1515-04	0.5%, 20ml	14.99	9.20	158.9%

b. The Schering Plough Group povided oher improper incentives

343. In addition to marketing the spread, The Schering Plough Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a

high invoice price. By utilizing "off-invoice" inducements, The Schering Plough Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

c. The Schering Plough Group has been the target of multiple government investigations

344. In connection with its scheme to inflate AWPs, The Schering Plough Group has been investigated by the Department of Justice, Texas Attorney General, West Virginia Attorney General, California Attorney General, California Bureau of Medi-Cal Fraud and Elder Abuse, and the Department of Health and Human Services Office of Inspector General, and the U.S. Attorney for the District of Massachusetts.

345. On May 30, 2003, Schering Plough announced that the U.S. Attorney for the District of Massachusetts had advised that its subsidiary, Schering Corporation, is the subject of a federal grand jury investigation. Schering Plough is the target of a criminal investigation involving: (i) providing remuneration, such as drug samples, to providers to induce the purchase of Schering products for which payment was made through federal health care programs; (ii) selling misbranded or unapproved drugs; (iii) submitting false wholesale pricing information for its pharmaceutical products to the government; and (iv) destroying evidence and obstructing justice relating to the government's investigation. *See* Schering Plough Press Release dated May 30, 2003, located at http://www.sch-plough.com/news/2003/business/20030530.html; "Schering Plough expects indictment," The Philadelphia Inquirer, at C3 (May 31, 2003). Moreover, according to Schering Plough's Form 10-K for the year 2000, this investigation has focused on "whether the AWP set by pharmaceutical companies for certain drugs improperly exceeds the average prices paid by dispensers . . . and other pricing and/or marketing practices."

346. A Medicaid investigation by the Texas Attorney General revealed that The Schering-Plough Group defrauded the State of Texas $14.5 million. Investigators determined that The Schering-Plough Group provided the greatest "spread" amongst the drug companies selling albuterol in Texas, and thereby obtained the largest market share for albuterol. The

Schering-Plough Group sold a box of albuterol to pharmacies for $13.50, while it charged the Texas Medicaid program $40.30, a 200% increase. *See Cornyn Sues Three Drug Companies for Medicaid Fraud*, Press Release by the Office of the Attorney General, State of Texas, Sept. 7, 2000. (www.oag.state.tx.us.gov)

347. On October 11, 2001, the West Virginia Attorney General filed suit against Warrick, alleging that Warrick defrauded state agencies and citizens by deliberately overstating the AWP for certain drugs, including albuterol, from approximately 1995 until December 2000.

348. In a report published by the DHHS (AB-00-86 (P006299-006316)), the DOJ documented at least one instance where the published AWPs for various dosages of albuterol sulfate manufactured by The Schering Plough Group were substantially higher than the actual prices listed by wholesalers. The following figures compare the DOJ's determination of an accurate AWP for one particular dosage, based upon wholesalers' price lists, with the AWP reported by The Schering Plough Group in the 2001 *Red Book*: The Schering-Plough Group reported to *Red Book* an AWP of $30.25 for albuterol sulfate, yet the DOJ determined the actual AWP to be $9.16, or $21.09 less.

349. As stated in a May 4, 2000, letter from U.S. Rep. Tom Bliley, Chairman of the Congressional Committee on Commerce, to Raman Kapur, President of Warrick:

> I am writing to you because one of the drugs reflecting a significant variation between the AWP-based prices paid by Medicare and the prices generally charged to private sector purchasers is albuterol sulfate, a drug manufactured by Warrick Pharmaceuticals.

(P006938-006941).

350. In his May 4, 2000, letter, Bliley outlined The Schering Plough Group's scheme with respect to the prescription drug albuterol sulfate. The government's investigation uncovered a significant spread between the amount Medicare reimbursed for albuterol sulfate and the amount the Schering-Plough Group actually charged. U.S. Rep. Bliley stated:

> The OIG [Office of the Inspector General] has determined that the Medicare-allowed amount for albuterol sulfate, a pharmaceutical product sold by your company, in the Fiscal Year 1996 was $.42.

> The OIG further estimated that the actual wholesale price of this drug was $.15 and the highest available wholesale price that the OIG was able to identify was $.21.

Id.

12. The Sicor Group (Sicor, Gensia and Gensia Sicor)

351. The Sicor Group engages in an organization-wide and deliberate scheme to inflate AWPs. The Sicor Group has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	acyclovir sodium	Anti-Infective Agent Used in the treatment of herpes infections
	amikacin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat respiratory tract, urinary tract, bone, skin and soft tissue infections
	amphotercin b	Antifungal Agent (Anti-Infective Agent) Used to help the body overcome serious fungus infections
	doxorubicin hydrochloride	Antineoplastic Used in the treatment of ovarian cancer and AIDS-related Kaposi's sarcoma
	etoposide	Mitotic Inhibitor (Antineoplastic) Used in the treatment of testicular neoplasm and small cell cancer of the lung
	leucovorin calcium	Antianemic Agent (Blood Modifier) Used in the treatment of anemia
	pentamidine isethionate	Anti-Infective Agent Used in the treatment of pneumonia
	tobramycin sulfate	Antibiotic Agent (Anti-Infective Agent) Used to treat severe infection

352. The specific drugs manufactured and/or distributed by The Sicor Group for which relief is currently sought in this case are set forth below or in Appendix A.

353. The Sicor Group controlled and set the AWPs for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. For example, by letter dated February 21, 1994, Gensia advised MediSpan of the impending launch of its new product called "Etoposide" and stated: "I have also include [sic] some guidelines in this pack for establishing Gensia's AWPs for our Etoposide." (SICOR 00955) (Confidential). That same day, Gensia sent a second letter to MediSpan stating, in part:

> The following represents the detailed information for this product and the AWP that we would like MediSpan to use:

ETOPOSIDE INJECTION

NDC #	PRODUCT DESC.	VIALSIZE	LIST PRICE	AWP
0703-5643-01	20MG/ML (100MG)	5ML	$105.16	$131.30
0703-5646-01	20MG/ML (500MG)	25ML	$483.74	$638.76

(SICOR 00956) (Highly Confidential).

354. Moreover, The Sicor Group has told its sales force to rely on the AWP information contained in the industry compendia when marketing to customers. For example, a memorandum dated April 6, 1994 to "Field Sales force" regarding "Average Wholesale Prices (AWP)" provides in pertinent part:

> Attached is a copy of Medi-Span's March 31, 1994 printout of product and AWP information for Gensia Laboratories. Since this information comes directly from Medi-Span's computer file, you will find it to be more accurate than the information that your customers are using from their reference texts. You will note, that the AWP information (listed in pack quantity) is found in the third column from the right. Additionally, the two columns to the immediate left of the AWP column represent: WAC (Wholesalers Acquisition Cost) and DP (Direct Price).

(SICOR 00753) (Highly Confidential).

355. The Sicor Group's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

a. The Sicor Group's understanding of AWP and intentional manipulation thereof

356. The Sicor Group has engaged in an ongoing deliberate scheme to inflate AWPs. For example, by letter dated September 25, 2000 to the HCFA administrator, the Chairman of the Commerce Committee revealed that: "[I]n 1998, a health care provider could buy Gensia's Etoposide for $14.00, while the AWP used to determine Medicare reimbursement was $141.97." (P007015-P007490).

357. The Sicor Group's marketing strategies further demonstrate its fraudulent practices. In a marketing document prepared by Gensia and obtained by the government in its investigation, Gensia stated:

> Concentrate field reps on the top 40 AIDS hospitals using a $54.00 price in conjunction with a 10% free goods program to mask the final price. Provides the account with an effective price of $48.60 per vial.

See letter dated September 28, 2000 from U.S. Rep. Pete Stark to Alan F. Holmer, President of the Pharmaceutical Research and Manufacturers of America. (P007512).

358. Certain handwritten notations appear on this same marketing document comparing the AWP with other prices used for the same drug:

FSS $44.95

Whls $71.00

Distr. $51.50

AWP $109.20

(P007532).

359. Similarly, a document entitled "Comparison of AWPs" based on the 1996 *Red Book* contains the following handwritten notation:

Rob, Joe,

Tim suggested sending this info to the reps. Your thoughts?

B

(SICOR 00756) (Highly Confidential). Following this notation is a chart comparing the AWPs for certain drugs published by various manufacturers, including Gensia. One example follows:

Doxorubicin		Abbott/ Adria	Bedford	FUSA	**Gensia**			
					X			
10		$48.31	$47.35	$44.50	**$49.29**	<Polymer		
					X			
50		$241.56	$236.74	$231.00	**$246.46**	<Polymer		
					X			

200		$946.94	$945.98	NA	**$966.14**	<Polymer		

Id.

360. Moreover, Gensia disseminated advertisements that actually contained a comparison of the Contract Price with the AWP and set forth the resulting spread (SICOR 00751, 00752) (Highly Confidential), because Gensia knew that marketing the spread was in its best interests. Realizing this, one customer of Gensia, Opti Care, sent a memorandum to all its offices (with a copy to Gensia) stating: "Gensia's products offer a significant spread between AWP and contract price. This spread may be attractive, when a payor's reimbursement is based on AWP and the drug is not MAC'd. (SICOR 00758) (Highly Confidential).

361. According to The Sicor Group's own documents, the published AWPs for its drugs were higher than the actual prices provided to wholesalers. In response to government subpoenas, The Sicor Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that The Sicor Group has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1 and 2 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of two Gensia drugs from a Medi-Span printout on which Gensia wanted its sales force to rely (the remaining drugs were redacted by The Sicor Group prior to production). (SICOR 00754-755) (Highly Confidential).

Table 1

Product	WAC	DP	AWP	DIFFERENCE (between AWP and DP)	PERCENTAGE SPREAD
Etoposide Inj	483.73	483.73	638.76	155.03	32%
Leucovorin CA Inj	32.50	32.50	40.63	8.13	25%

362. Table 2 is an analysis of certain dosages of four Gensia drugs from multiple Gensia price lists for a particular customer, Pharmaceutical Buyers, Inc., comparing the customer's Contract Price with the AWP and the resulting spread (the remaining drugs were

redacted by The Sicor Group prior to production). (SICOR 00555, 573, 614, 633) (Highly Confidential).

Table 2

Product	AWP	PBI CONTRACT	SPREAD	PERCENTAGE SPREAD
DOXORUBICIN HYDROCHLORIDE	871.70	293.60	578.10	1,969%
ETOPOSIDE	1207.33	456.00	751.33	1,648%
LEUCOVORIN CALCIUM	39.00	4.58	34.42	752%
PENTAMIDINE ISETHIONATE	468.00	193.75	274.25	1,415%

363. The following are additional examples of drugs whose AWPs were inflated:

Manufacturer	Drug Name	NDC	Quantity	1999 AWP *Red Book*	W-Sale Spread	%
Gensia	Doxorubicin Hydrochloride (INJ, IJ {M.D.V., Polymer})	00703-5040-01	2 mg/ml, 100 ml	350.00	204.00	139.7%
Gensia	Doxorubicin Hydrochloride (INJ, IJ {M.D.V., Polymer})	00703-5040-01	2 mg/ml, 100 ml	350.00	212.00	153.6%
Gensia	Doxorubicin Hydrochloride (INJ, IJ {S.D.V., Polymer})	00703-5043-63	2 mg/ml, 5 ml	17.50	6.70	62.0%
Gensia	Doxorubicin Hydrochloride (INJ, IJ {S.D.V., Polymer})	00703-5043-63	2 mg/ml, 5 ml	17.50	4.40	33.6%
Gensia	Doxorubicin Hydrochloride (INJ, IJ {S.D.V., Polymer})	00703-5043-63	2 mg/ml, 5 ml	17.50	3.50	25.0%
Gensia	Doxorubicin Hydrochloride (INJ, IJ {S.D.V., Polymer})	00703-5046-01	2 mg/ml, 25 ml	87.50	51.50	143.1%
Gensia	Doxorubicin Hydrochloride (INJ, IJ {S.D.V., Polymer})	00703-5046-01	2 mg/ml, 25 ml	87.50	52.50	150.0%
Gensia	Etopside (INJ, IJ {BULK PACKAGE})	00703-5668-01	20 mg/ml, 50 ml	1,338.13	1,257.13	1552.0%
Gensia	Etopside (INJ, IJ {BULK PACKAGE})	00703-5668-01	20 mg/ml, 50 ml	1,338.13	1,261.87	1654.7%

Manufacturer	Drug Name	NDC	Quantity	1999 AWP *Red Book*	W-Sale Spread	%
Gensia	Etopside (INJ, IJ {M.D.V. POLYMER})	00703-5653-01	20 mg/ml, 5 ml	46.25	39.25	560.7%
Gensia	Etopside (INJ, IJ {M.D.V.})	00703-5646-01	20 mg/ml, 25 ml	220.00	179.00	436.6%
Gensia	Etopside (INJ, IJ {M.D.V.})	00703-5646-01	20 mg/ml, 25 ml	220.00	181.00	464.1%
Gensia	Leucovorin Calcium (PDI, IJ {P.F. VIAL})	00703-5140-01	100 mg ea	38.63	33.73	688.4%
Gensia	Leucovorin Calcium (PDI, IJ {P.F. VIAL})	00703-5140-01	100 mg ea	38.63	35.84	1284.6%
Gensia	Leucovorin Calcium (PDI, IJ {P.F. VIAL})	00703-5145-01	350 mg ea	85.75	64.75	308.3%
Gensia	Leucovorin Calcium (PDI, IJ {P.F. VIAL})	00703-5145-01	350 mg ea	85.75	71.75	512.5%
Gensia	Leucovorin Calcium (PDI, IJ {P.F. VIAL})	00703-5145-01	350 mg ea	85.75	73.25	586.0%
Gensia	Pentamidine Isethionate (PDI, IJ {S.D.V.})	00053-1000-05	300 mg ea	0.00	-29.00	-100.0%
Gensia	Tobramycin Sulfate (INJ, IJ {M.D.V.})	00703-9402-04	40 mg/ml, 2 ml	13.68	10.68	356.0%
Gensia	Tobramycin Sulfate (INJ, IJ {M.D.V.})	00703-9402-04	40 mg/ml, 2 ml	13.68	2.73	24.9%
Gensia	Tobramycin Sulfate (INJ, IJ {M.D.V.})	00703-9416-01	40 mg/ml, 30 ml	73.25	36.35	98.5%

364. In addition, the artificial inflation of AWP is also evidenced by the fact the AWP for certain drugs remained the same while the true cost decreased. For example:

Company	Drug	NDC	Date	AWP	True Cost
Gensia	Etoposide	00703-5643-01	8/94	$141.97	$85.00
Gensia	Etoposide	00703-5643-01	4/95	$141.97	$67.62
Gensia	Etoposide	00703-5643-01	10/95	$141.97	$49.00
Gensia	Etoposide	00703-5643-01	2/96	$141.97	$36.00
Gensia	Etoposide	00703-5643-01	9/96	$141.97	$18.00
Gensia	Etoposide	00703-5643-01	1/97	$141.97	$14.00

365. If the true cost was decreasing as set forth above, then the AWP should have been decreasing as well.

b. The Sicor Group provided other improper incentives

366. In addition to marketing the spread, The Sicor Group has utilized other impermissible inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. By utilizing "off-invoice" inducements, such as free goods, The Sicor Group provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price. (SICOR 00718, 04182, 00689) (Highly Confidential).

c. The Sicor Group has been the target of multiple government investigations

367. In connection with its scheme to inflate AWPs, The Sicor Group has been investigated by the Department of Justice, Department of Health and Human Services Office of Inspector General, the Texas Department of Health, and the California Attorney General.

368. In a report published by the DHHS, the DOJ documented at least 17 instances where the published AWPs for various dosages of drugs manufactured by The Sicor Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by The Sicor Group in the 2001 *Red Book*.

Drug	The Sicor Group's 2001 *Red Book* AWP	DOJ Determined Actual AWP	Difference	Spread
Acyclovir Sodium	$125.00[8]	$100.00	$25.00	25%
Amikacin Sulfate	$87.50	$72.68	$14.82	20%
Tobramycin Sulfate	$342.19	$6.98	$335.21	4,802%

[8] Calculation based on the AWP listed in the 2000 *Red Book*.

(P006299-006316).

13. Watson

369. Watson engages in an organization-wide and deliberate scheme to inflate AWPs. Watson has stated fraudulent AWPs for all or almost all of its drugs, including those set forth below.

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
Ferrlecit	sodium ferric gluconate complex in sucrose injection	Iron Preparation (Blood modifier) Used for treatment of anemia in patients undergoing hemodialysis
InfeD	iron dextran	Iron Preparation (Blood modifier); Nutritional Supplement Used for treatment of iron deficiency
	dexamethasone acetate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral adema
	dexamethasone sodium phosphate	Hormone; Glucocorticoid Used to treat inflammatory conditions, hematologic disorders and cerebral adema
	diazepam	Central Nervous System Agent Used to treat status eplipeticus and anxiety disorders. Also used as an amnesic prior to surgical procedures
	estradiol	Estrogen (Hormone) Used for treatment of menopausal symptoms and postmenopausal osteoporosis
	fluphenazine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used to manage psychotic disorders
	gemfibrozil	Antilipemic Agent (Cardiovascular Agent) Used to lower cholesterol
	gentamicin sulfate	Anti-Infective Agent Used as a general antibiotic to treat serious gastrointestinal, respiratory, bone, skin and soft tissue infections
	imipramine hcl	Central Nervous System Agent; Psychotherapeutic Agent Used in the treatment of depression
	lorazepam	Central Nervous System Agent Used for treatment of anxiety disorders
	nadolol	Antihypertensive (Cardiovascular Agent) Used in the treatment of hypertension and management of angina
	perphenazine	Central Nervous System Agent; Psychotherapeutic Agent Used to manage psychotic disorders
	propanolol hcl	Beta Adrenergic Blocking Agent (Cardiovascular Agent) Used to treat hypertension

Brand Name (if applicable)	Generic Name	Therapeutic Category/Usage
	ranitidine hcl	Histamine Receptor Antagonist (Gastrointestinal Agent) Used for treatment of duodenal ulcer, gastric ulcer, gastroesophagael disease and heartburn
	vancomycin hcl	Antibiotic Agent (Anti-Infective Agent) Used as a general antibiotic
	verapamil hcl	Calcium Channel Blocker (Cardiovascular Agent) Used in the treatment of tachyarrhythmia, angina and hypertension

370. The specific drugs manufactured and/or distributed by Watson for which relief is currently sought in this case are set forth below or in Appendix A.

371. Watson controlled and set the AWPs for all of its drugs, including those appearing in Appendix A, through direct communications with industry compendia. For example, a Watson memo states that it is faxing prices to various pricing services, but "not all pricing services received all of the prices listed on this letter. Most only received the AWP price..." The memo goes on to state that "AWP is the primary price being communicated in these faxes to establish a reference for reimbursement." (MDLW25203) (Highly Confidential). Further, a *Red Book* Product Listing Verification form asks for approval of changes to the stated AWP for Schein's (which was later acquired by Watson) Verapamil HCL, Vinblastine Sulfate and Vincristine Sulfate. A Schein executive okayed the changes and signed the *Red Book* form. (MDLW00887).

372. Watson's scheme to inflate its reported AWPs and market the resulting spread to increase the market share of its drugs has resulted in excessive overpayments by the State of Nevada and Nevada citizens.

a. Watson's understanding of AWP and intentional manipulation thereof

373. Watson plainly recognizes that "AWP drives reimbursement." (MDLW12564) (Highly Confidential).

374. When deciding where to set the price for its drug Ferrlecit, Watson recognized that, in a Medicare Reimbursement Mechanism, "margin drives AWP and ASP" and that a goal

of setting the price is that "profit margin at the unit level must not decrease." Watson recognizes that 20% of reimbursement is patient co-pay, which can be private insurance, Medicaid or cash. (MDLW05457-05460) (Highly Confidential).

375. Watson was well aware that payors relied on the AWP, and was sensitive to avoid alerting payors to Watson's AWP manipulation. In the context of a pricing study, a Schein executive noted that "it would be great to get a read from some HCFA personnel regarding what level of price will set off alarms with reimbursement." (MDLW25216) (Highly Confidential).

376. In that same document, Watson acknowledges that AWP manipulation is the key to its customers' profits "if through reimbursement we can maintain or increase the money a unit makes on using this product does the price even matter?" (MDLW25216) (Highly Confidential).

377. In response to government subpoenas, Watson produced numerous price lists setting forth spreads between AWP and prices offered to wholesalers, providers and other intermediaries. A review of those lists indicates that Watson has consistently offered drugs to its customers at prices significantly below the published AWP, and that the spread was of great importance to Watson's customers. It is not practical to repeat every one of those drugs and the spread offered to specific customers. However, set forth below in Table 1 are a number of those drugs (not already referenced above) and the substantial spread offered to Watson customers.

378. Table 1 is an analysis of certain dosages of Schein drugs from a chart titled Schein Product Status Report, February 1996. (MDLW01237).

Table 1

Drug	AWP	WAC	% Spread
Fluphenazine HCL 1mg	$46.08	$15.71	193%
Gemfibrozil 600mg	$55.65	$7.95	600%
Imipramine HCL 10mg	$4.45	$1.32	237%
Nadolol 20mg	$85.32	$42.95	98%
Perphenazine 2mg	$42.53	$19.76	115%

b. Watson provided other improper incentives

379. In addition to marketing the spread, Watson has utilized other inducements to stimulate sales of its drugs. These inducements were designed to result in a lower net cost to the provider while concealing the actual wholesale price beneath a high invoice price. In one instance in May 2000, Schein offered "Priority Customers" an additional 5% discount on Ferrlecit "off invoice" for all purchases made that month. (MDLW15896.) By utilizing "off-invoice" inducements, Watson provided purchasers with substantial discounts meant to gain their patronage while maintaining the fiction of a higher wholesale price.

c. Watson has been the target of multiple government investigations

380. In connection with its scheme to inflate AWPs, Watson has been investigated by the Department of Justice, the Department of Health and Human Services Office of Inspector General, and the State of California.

381. In a report published by the DHHS (AB-00-86), the DOJ documented at least 12 instances where the published AWPs for various dosages of drugs manufactured by Watson were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP for that particular dosage, based upon wholesalers' price lists, with the AWP reported by Watson in the *Red Book*.

Drug	Watson's 1998-2001 *Red Book* AWPs	DOJ Determined Actual AWP	Difference	Spread
Dexamethasone Acetate	$46.45 (1998)	$11.50	$34.95	304%
Dexamethasone Sodium Phosphate	$93.04 (2001)	$1.08	$91.96	851%
Diazepam	$18.15 (2000)	$2.50	$15.65	626%
Gentamicin Sulfate	$114.10 (1999)	$1.18	$112.92	957%
Iron Dextran	$377.04 (2001)	$24.69	$352.35	1,427%
Testosterone Ethanate	$42.10 (2001)	$13.39	$28.71	214%
Vancomycin HCL	$70.00 (1998)	$3.84	$60.16	1,567%

(P006299-P006316).

d. Watson Concealed Its AWP Manipulation

382. Watson deliberately acted to conceal its fraudulent reporting and marketing of the AWP spread. For example, as noted above, Watson reported its AWP to various industry compendia, but disclosed WAC, direct price and average sale price to only a very few, if any, outside entities. (MDLW25204) (Highly Confidential). Also as noted above, Watson needed to keep the AWP high, but at a level that would not "set off alarms with reimbursement" (MDLW25216) (Highly Confidential). Watson effectively hid the AWP spread.

VIII. DEFENDANTS' "BEST PRICE" FRAUDS

A. Medicaid Drug Rebate Program

383. For a manufacturer's drug to be eligible for Medicaid coverage, the manufacturer must sign a drug rebate agreement with the Center for Medicare and Medicaid Services ("CMS"). 42 U.S.C. § 1396r-8.

384. Pursuant to this agreement, the manufacturer pays quarterly rebates intended to afford Medicaid access to a maufacturer's "Best Price."

385. The rebates are calculated as follows.

386. For all drugs other than single source drugs and innovator multiple source drugs (*i.e.,* generics), the rebate is equal to 11% of the drug's AMP. 42 U.S.C. § 1396r-8(c)(3).[9]

387. AMP is the average price paid to the manufacturer for the drug in the United States during the rebate period by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts. 42 U.S.C. § 1396r-8(k). The model Rebate Agreement provides a more detailed definition:

> [T]he average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. ***AMP includes cash discounts allowed and all other price reductions* (other than Medicaid rebates), *which reduce the actual price***

[9] The percentage was 10% for rebate periods prior to January 1, 1994.

> ***paid***. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements).

Rebate Agreement at ¶ 1(a) (emphasis added).

388. For each dosage form and strength of single source and innovator multiple source drugs (*i.e.*, "brand name" drugs), the rebate is the greater of: (i) the AMP less the best price; or (ii) AMP multiplied by the "minimum rebate percentage," which is presently 15.1%. 42 U.S.C. § 1396r-8(c)(1)(A).[10] The rebate is adjusted upward for any price increase for a product that exceeds the increase in the Consumer Price Index-Urban for all items since the fall of 1990. 42 U.S.C. § 1396r-8(c)(2).

389. "Best Price" means, with respect to single source drugs and innovator multiple source drugs, the ***lowest price*** at which the manufacturer sells the drug to any purchaser in the United States (including any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity[11]) during the rebate quarter. The Best Price ***shall be inclusive*** of cash discounts, free goods, volume discounts and rebates (other than rebates under the Medicaid statute); shall be determined without regard to special packaging, labeling or identifiers on the dosage form or product or package; and shall not take into account prices that are nominal in amount. 42 U.S.C. § 1396r-8(c)(1)(C). The model Rebate Agreement published on the CMS website adds that "[t]he best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." Rebate Agreement at ¶ 1(d).

390. The OIG recently reemphasized the importance of accurately reporting AMPs and Best Prices in its April 2003 report titled "Compliance Program Guidance for Pharmaceutical

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[10] The minimum rebate percentages by rebate period are as follows: 12.5% after Dec. 31, 1990 and before Oct. 1, 1992; 15.7% after Sept. 30, 1992 and before Jan. 1, 1994; 15.4% after Dec. 31, 1993 and before Jan. 1, 1995; 15.2% after Dec. 31, 1995 and before Jan. 1, 1996: 15.2%; and 15.1% after Dec. 31, 1995: 15.1%.

[11] But excluding the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, the Public Health Service, prices charged under the Federal Supply Schedule of the General Services Administration, prices used under a State pharmaceutical assistance program, and any depot prices and single award contract prices of any federal agency.

Manufacturers:" "Given the importance of the Medicaid Rebate Program, as well as other programs that rely on Medicaid Rebate Program benchmarks (such as the 340B Program . . .), manufacturers should pay particular attention to ensuring that they are calculating Average Manufacturer Price and Best Price accurately and that they are paying appropriate rebate amounts for their drugs." OIG COMPLIANCE PROGRAM at 12.

391. The OIG also reemphasized the importance of including all discounting arrangements in best price:

> Discounting arrangements are prevalent in the pharmaceutical industry and deserve careful scrutiny particularly because of their potential to implicate the Best Price requirements of the Medicaid Rebate Program. Because the Medicaid Rebate Program in many instances requires that states receive rebates based on the Best Price offered by a pharmaceutical manufacturer to other purchasers, manufacturers have a strong financial incentive to hide *de facto* pricing concessions to other purchasers to avoid passing on the same discount to the states. Because of the potential direct and substantial effect of such practices on federal health care program expenditures and the interest of some manufacturers in avoiding price concessions that would trigger rebates to the states, any remuneration from a manufacturer to a purchaser, however characterized, should be carefully scrutinized. [OIG COMPLIANCE PROGRAM at 18.]

B. Defendants Have Reported False AMP And Best Price Information, Resulting In The Underpayment Of Drug Rebates

392. In keeping with their artificial price inflation scheme, each defendant did not report the actual Best Price or AMP, but instead (i) reported higher prices and (ii) excluded discounts and other inducements offered to physicians, such as free goods, volume discounts, rebates, educational grants and other programs that lower the providers' actual cost of the drugs, that resulted in lower prices than the prices reported to the Medicaid Program (and, consequently, the payment of lower rebates).

393. Excluding sales to HMO repackagers from drug manufacturer Best Price determinations has been an area of documented abuse. Sales to HMO repackagers are specifically required to be included in the Best Price, yet some manufacturers have failed to do so.

394. In 2001, OIG documented that, for the manufacturers of the top 200 Medicaid reimbursed drugs for Fiscal Year 1999, seven manufacturers excluded sales to eight repackagers, three of which were HMO repackagers.[12] As a result, Medicaid drug rebates totaling $80.7 million for Fiscal Year 1999 were lost. In Fiscal year 1998, drug rebates totaling $27.8 million were lost becase sales to HMOs were excluded from Best Price determinations. In short, these drug manufacturers were selling the drugs to the repackagers at prices significantly below the manufaturers' reported Best Prices. In some instances, the sales to the HMOs were at prices as much as 75 percent below the reported Best Price. OIG MEDICAID DRUG REBATES – SALES TO REPACKAGERS EXCLUDED FROM BEST PRICE DETERMINATIONS at 1, 4 (March 2001).

395. Another method by which drug manufacturers "hide" rebates that go unincluded in their AMP and Best Price reporting is through the use of "credit memos." Drug manufacturers rarely print and mail a physical check when they provide rebates, because they create a paper trail that is identifiable as a rebate. Instead, they issue "credit memos" electronically through a wholesaler's computer system. Furthermore, manufacturers also disguise the purpose of the credit memo by noting, for instance, that the credit memo was issued for "returned goods" when, in fact, it was not. On information and belief, all defendants have used credit memos to provide discounts and/or rebates that are then not included in the AMP and Best Prices reported by defendants each quarter.

396. On information and belief for the drugs identified for each defendant, as having inflated AWPs, due to the provisions of rebates, free samples, discounts and the other devices set forth above, the creation of a phony AWP also resulted in the best price not being paid to the state.

397. Some exemplary misconduct in the arena of Best Price reporting generally include the following:

[12] The OIG report did not identify the drugs or the manufacturers.

1. AstraZeneca: Zoladex

398. Zoladex is a physician-administered drug used largerly as a treatment for prostate cancer.

399. An investigation conducted by United States Attorney's Office for the District of Delaware revealed that AstraZeneca knowingly misreported and underpaid Medicaid rebates for Zoladex by failing to include in its reported Best Price off invoice price concessions provided in various forms including, but not limited to, cash discounts in the form of grants, services, freegoods contingent on a purchase requirement, volume discounts and rebates.

400. As noted earlier, the investigation resulted in a criminal guilty plea and the payment of $355 million in criminal penalties and civil damages and penalties, part of which related to the Zoladex best price scam.

2. Pfizer: Lipitor

401. In 1999, Warner-Lambert (now part of defendant Pfizer) offered and paid educational grants to a managed care organization in exchange for the MCO's agreement to extend unrestricted formulary status to Warner-Lambert's Lipitor drug.

402. Contrary to the requirements of the Medicaid Drug Rebate Program, the value of the grants was not reported to CMS in the Best Price. As a result, Warner-Lambert underpaid rebates due the states by about $21 million.

403. Pfizer recently settled the charges by paying $49 million. OIG SEMIANNUAL REPORT TO THE CONGRESS (OCTOBER 2002-MARCH 2003) at 22.

IX. DEFENDANTS' CONCEALMENT OF THE TRUTH AND TOLLING OF STATUTES OF LIMITATION

404. Each defendant concealed its fraudulent conduct from the State of Nevada and others by controlling the process by which the AWPs for drugs were set. Defendants prevented the State of Nevada and others from knowing what the actual pricing structures for these drugs were, and failed to inform them of the usage of free samples and the provision of other financial

incentives to providers and other intermediaries to lower their respective costs for the drugs. Moreover, defendants' fraudulent conduct was of such a nature as to be self-concealing.

405. Each defendant closely guarded its pricing structures and marketing plans from public disclosure. For example, a recent CMS Health Care Industry Market Update (dated January 10, 2003) stated that drug "price discounts are closely guarded as competitive information." *See* p. 39.

406. Each defendant also concealed its fraudulent conduct by instructing providers and others not to report the prices they paid for drugs.

407. Each defendant also worked with and motivated provider and intermediary trade associations to halt any investigations or change in the AWP system.

408. Each defendant's efforts to conceal its pricing structures for drugs is evidence that it knew that its conduct was fraudulent.

409. Thus, each defendant concealed that (i) its AWPs were highly-inflated (and were inflated to cause the Nevada Medicaid Program and other reimbursement programs and Patients making co-pays to overpay for drugs); (ii) it was manipulating the AWPs of the drugs; (iii) its inflated AWPs greatly exceeded the average of the wholesale prices based upon a good faith and reasonable estimate utilizing the pricing and transaction information available to the defendant in conducting its ordinary business affairs; and (iv) it was not reporting true Best Prices and paying the full rebates due Medicaid.

410. Nevada was diligent in pursuing an investigation of the claims asserted in this Amended Complaint. Through no fault of its own, Nevada did not receive inquiry notice nor learn of the factual basis for its claims in this Complaint and the injuries suffered therefrom until recently.

411. Any applicable statutes of limitations have been tolled by defendants' knowing and active concealment and denial of the facts alleged herein. Nevada has been kept in ignorance of vital information essential to knowledge of and the pursuit of these claims, without

any fault or lack of diligence on its part. The State could not reasonably have discovered the fraudulent nature of the published AWPs and Best Prices.

412. Defendants were and continue to be under a continuing duty to disclose to Nevada the fact that the published AWPs bore and continue to bear no relationship to the prices or pricing structures for drugs. Because of their knowing, affirmative, and/or active concealment of the fraudulent nature of the published AWPs, defendants are estopped from relying on any statutes of limitations.

X. DIRECT DAMAGE SUSTAINED BY THE STATE OF NEVADA, PATIENTS AND THIRD-PARTY PAYORS

413. Patients are directly damaged by defendants' AWP Inflation Scheme because Patients frequently are required to make a co-payment for a pharmaceutical, or because Patients occasionally make payment in full. As explained in greater detail above, the amount of the co-payment is often a direct function of the overall reimbursement paid on behalf of the patient by Medicare or Third-Party Payors.

414. For example, as alleged herein, Medicare recipients must pay 20% of the total amount that is reimbursed by Medicare to the pharmaceutical manufacturer. Thus, if Medicare reimburses $100 for a covered drug based upon the reported AWP, the Medicare beneficiary is responsible for 20% (or $20) in this situation.

415. An example of the dramatic impact of AWP inflation on Patients is provided by reviewing the typical drug treatment regimen for a stage II breast cancer Medicare patient with a body surface are of approximately two meters.

416. The treatment consists of four chemotherapy infusion treatments given at three-week intervals. Dosages have been totaled to reflect the quantities administered over the 12 week chemotherapy period:

Drug Name	Mfr.	Dosage/ treatment x 4 treatment cycles	Estimated cost of treatment x 4 treatment cycles	AWP cost of treatment x 4 treatment cycles	Spread %	Spread in $	Patient co-pay based on wholesale prices	Patient Co-Pay based on AWP prices	Additional Co-pay created by inflated AWP
Adriamycin	BMS	480mg	$1,062.6	$2,649.91	59.9%	$1,587.31	212.52	529.82	$317.3
Cytoxan		4,800mg	237.02	$237.02	0%	$0	47.04	47.04	$0
Decadron (IV)		40mg	$830.88	$1097.10	14.8%	$266.22	166.18	219.42	$53.24
Anzemet (IV)	Aventis	400mg	$591.08	$666.00	11.25%	$74.92	118.22	133.2	$14.98
TOTAL			**$2,721.54**	**$4,650.03**		**$1,928.45**	**$543.96**	**929.48**	**$385.52**

417. Thus, over one-third of the Medicare co-payment results from AWP inflation.

418. Many Medicare beneficiaries obtain supplemental insurance known as "Medigap" or "Medicare Plus" to cover the costs of pharmaceuticals as well as other costs not paid by Medicare. Such supplemental insurers are also Third-Party Payors who are damaged by the AWP Inflation Scheme.

419. The AWP Inflation Scheme also affected the State of Nevada because, in each instance of a drug payment made under Medicaid, the State paid an inflated amount.

420. Moreover, each of the defendants has failed to report accurate Best Price information as required by federal Medicaid law, and thereby deprived the State of its proper rebates. *See* 42 U.S.C. § 1396r-8.

421. Similarly, numerous State agencies have overpaid for medications based upon the fraudulently reported AWPs.

422. In addition, Third-Party Payors also typically make reimbursement to health care providers for pharmaceuticals based upon the AWP. They have made inflated reimbursement payments based on defendants AWP Inflation Scheme.

XI. CLAIMS FOR RELIEF

COUNT I

DECEPTIVE TRADE PRACTICES (Violations of NRS 598.0903, *et seq.*)

CLAIM FOR DAMAGES CAUSED TO NEVADA RESIDENTS

423. The State of Nevada repeats and realleges the preceding paragraphs of this Amended Complaint as if fully set forth herein.

424. This Claim is brought for restitution of the losses incurred by Nevada residents as a result of the AWP Inflation Scheme.

425. Defendants' conduct as alleged in this Amended Complaint constitutes deceptive acts or practices in violation of NRS 598.0915(13), 598.0915(15), and 598.0923(3) in that:

> (a) Defendants have failed to disclose material facts in connection with the sale of goods in that they have not disclosed that their AWPs greatly exceeded the average of the wholesale prices based upon a good faith and reasonable estimate utilizing the pricing and transaction information available to defendants in conducting their ordinary business affairs, but were instead inflated in order to drive up the prices paid by Patients and Third-Party Payors within the State of Nevada;
>
> (b) Defendants have made false or misleading statements of facts concerning the price of goods in that they have made deceptive statements about the true AWP paid for their medications in order to drive up the prices paid by Patients within the State of Nevada;
>
> (c) Defendants have knowingly made false representations in a transaction by representing that the AWP is an accurate reflection of the average wholesale price paid for their drugs; and
>
> (d) Defendants have violated state and federal statutes and regulations relating to the sale or lease of goods including, without limitation, the Nevada RICO statute (NRS 207.470 *et seq.*), the federal regulations governing the determination of Medicare payments for drugs (42 C.F.R. § 405.517), the federal mail and wire fraud statutes, 18 U.S.C. §§ 1341 and 1343 and the Racketeer Influenced and Corrupt Organizations Act (RICO), particularly 18 U.S.C. § 1962(c) & (d).

426. Defendants acted willfully and knowingly in committing the actions set forth above.

427. The wrongful conduct alleged in this Amended Complaint occurs and continues to occur in the ordinary course of defendants' business or occupation and has caused great harm to the State of Nevada and its residents, who were foreseeable and direct victims of defendants' wrongful conduct.

428. Defendants' violations of the Deceptive Trade Practices Act were committed with the intent to mislead and defraud.

429. Defendants' wrongful, deceptive and illegal conduct has resulted in excessive and illegal profits to defendants and excessive payments made by Patients who are Nevada residents.

WHEREFORE, the State of Nevada prays as follows:

A. That the Court adjudge and decree that defendants have engaged in the conduct alleged herein.

B. That the Court adjudge that the conduct is unlawful and in violation of NRS 598.0915(13), 598.0915(15) and 598.0923(3).

C. That the Court enjoin and restrain defendants and their officers, agents, servants, and employees, and those in active concert or participation with them, from continuing to engage in such conduct or other conduct having similar purpose or effect.

D. That the Court enjoin defendants and order that any and all future disseminations of AWP accurately reflect the average of wholesale prices based upon a good faith and reasonable estimate utilizing the pricing and transaction information available to the defendant in conducting their ordinary business affairs.

E. That, pursuant to NRS 598.0993, the Court make such orders or judgments as may be necessary to restore to Patients who reside in the State of Nevada all moneys which defendants acquired from them by means of any of the deceptive trade practices complained of herein.

F. That the State of Nevada recover from defendants the costs of this action, including reasonable attorneys' fees.

G. That the Court Order such other and further relief as it may deem just, necessary and appropriate.

COUNT II

DECEPTIVE TRADE PRACTICES DIRECTED AT ELDERLY NEVADA RESIDENTS (Violations of NRS 598.0973)